**WWW trial Statistical Analysis Plan**

**Efficacy of a brief public health intervention to prevent weight gain during the Christmas holiday period: randomised controlled trial and nested qualitative study**

**ISRCTN15071781**

**Study design**

A pragmatic randomised controlled trial comparing a behavioural intervention versus comparator to prevent weight gain over the Christmas holiday period.

**Population**

Adults with a BMI of 20 or more.

**Primary outcome**

Difference in change in weight (kg) from baseline to post Christmas follow up (5-8 weeks).

**Sample size**

The standard approach to sample size calculation is to aim to detect a worthwhile intervention effect. This is difficult here because there is a linear relation between overweight and mortality (30% increase per 5 kg/m2) (1). We proposed a sample size based on the likely size of effect we expected to achieve, 0.75kg difference in weight between the groups at follow up. A total of 226 participants provides 80% power to detect 0.75 kg (SD=2.0) (2) difference in change in weight between the groups with 5% significance. This rises to 284 with an allowance for 20% loss to follow up. We chose this difference in weight because the intervention is very brief and evidence shows that even small amounts of weight prevention maintained over the lifetime has important health benefits (3).

**General considerations**

*Levels of confidence and p-values*

P values from two tailed tests will be presented along with corresponding 95% confidence intervals.

*Intention to treat analysis*

Data will be analysed on the intention to treat basis.

*Missing data*

If <5% of participants are missing the primary outcome (weight) they will be excluded from the analysis. If loss to follow up is ≥ 5% we will perform multiple imputation for the primary analysis based on the following variables: sex, BMI, age, ethnicity and socio-economic status (IMD score). Self-reported weight will be used in the analyses if objective weights are not available.

*Timing of interim analyses*

Due to the short time period between baseline and follow up assessments no interim analyses will be performed. No stopping rules are proposed.

*Timing of main analyses for dissemination*

The first set of analyses will be made available for public dissemination 12 months after the last participant has completed follow up. Analyses will be undertaken 3 months after completion of the last follow up.

**Proposed analyses**

*Route of recruitment and baseline characteristics*

Participants will be summarised by randomisation group according to route of recruitment (schools, workplaces & social media), age, gender, ethnicity (white or non-white), deprivation quartile (based on postcode), height (cm), weight (kg), BMI (category), employment status, marital status, education status, number of children living at home, celebrating any social or religious occasions (including Christmas) in next few weeks (yes/no), currently attending a commercial weight loss programme (attending/non-attending), ever tried to lose weight (yes/no), hours sitting each day (0-3, 4-7, 8-10, 11+), know anybody else in the study (yes/no), alcohol consumption (units per week), frequency of physical activity per week (never, once, 2-3 times, 4-5 times, 6+ times), frequency of self-weighing per week (every day, 6-5 times, 4-3 times, 2 times, once, less than once per week), smoking status (yes/no), currently trying to lose weight/maintain/not trying to lose or maintain weight, following a weight loss diet (yes/no), taking medication to control weight (yes/no) and ever had weight loss surgery (yes/no). Categorical data will be summarised by numbers and percentage. Continuous data will be summarised by mean and standard deviation or median and interquartile range if data are skewed.

*Primary analysis*

The primary outcome is the difference in weight change between the randomisation arms (analysis will use weight at follow up adjusted for baseline weight and the stratification variable of attending a commercial weight loss programme) and will be assessed by linear regression. Data transformation, non parametric approaches or bootstrap methods may be utilised if there is evidence of skewness in residual distributions. Difference in weight change between the randomisation groups will be presented as adjusted means and 95% confidence intervals together with associated p values. The unadjusted change in weight for both groups will also be presented.

Secondary analyses/outcomes

The primary outcome analysis will be repeated with additional covariates (BMI (if there are no issues with collinearity) and time between baseline and follow up: days). Other continuous secondary outcomes (see below) will be analysed in the same way as the primary outcome (adjusted for the stratification variable) and repeated with the additional covariates (BMI and time between baseline and follow up). The continuous secondary outcomes are percentage body fat, emotional eating, cognitive restraint of eating behaviour and uncontrolled eating (as measured by the three factor eating questionnaire).

A further secondary outcome is participants gaining no more than 0.5 kg of their baseline weight at follow up. The comparison across the two study arms will be made using logistic regression, adjusting for the stratification variable comparing the odds of gaining no more than 0.5 kg in the intervention group to the odds in the comparator group at follow up. Further models adjusting for the additional covariates (BMI and time between baseline and follow up) will be developed. The results will be presented as adjusted odds ratios, 95% confidence intervals and associated p values.

*Subgroup analyses:*

We are not expecting any subgroup differences and are therefore performing exploratory subgroup analyses. The following pre-defined subgroups will be compared for the primary outcome by their inclusion as an interaction term (intervention by participant characteristics) in the modelling.

(1) BMI baseline

(2) Participants who adhered to weekly self weighing as measured using the weight record cards (adherers or non adherers). Two definitions of assessing intervention adherence will be used; these are minimum and high adherence. Minimum adherers are defined as participants who weighed themselves and recorded their weight on the record card at least twice a week for 75% of weeks prior to their follow up. High adherers are defined as participants who weighed themselves and recorded their weight on the record card at least five times a week for 75% of weeks prior to their follow up.

*Process measures*

Follow up data from the intervention group about their views of regular self weighing will be summarised as means and standard deviations (individual item scores). Index of habit strength scores in the intervention group at follow up will be summarised as means and standard deviations (scale total scores).

In the intervention group, assessment of whether frequency of self-weighing during the intervention period (from the weight record card data) is associated with cognitive restraint of eating at follow up will be explored using linear regression analysis (adjusting for cognitive restraint baseline score).

In both groups, assessment of whether frequency of self-weighing (using the single item score) at follow up) is associated with weight gain prevention.

*Descriptive follow up data*

Additional descriptive data collected at follow up will be summarised by randomisation group: stayed away from home during the study (yes/no), if stayed away from home, how many nights (number of nights), alcohol consumption (units per week), frequency of physical activity per week (never, once, 2-3 times, 4-5 times, 6+ times), frequency of self-weighing per week (all participants) (every day, 6-5 times, 4-3 times, 2 times, once, less than once per week), number of children living at home, currently trying to lose/maintain/not trying to lose or maintain weight, attending a commercial weight loss programme (attenders/non-attenders) and following a weight loss plan, taking medication to control weight, do you know anyone else in the study (yes/no), if yes, did you discuss the study with them (yes/no), have you been hospitalised since baseline (yes/no) and have you done anything specifically to maintain your weight (yes/no). Categorical data will be summarised by numbers and percentages. Continuous data will be summarised by mean and standard deviation or median and interquartile range if data are skewed.

**References**

1.Prospective Studies Collaboration. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet 2009;373:1083-96.

2. Lally P, Chipperfield A, Wardle J. Healthy habits: efficacy of simple advice on weight control based on a habit formation model. I J Obes 2008;32:700-7.

3.NICE. Obesity Guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. In: 43 NCG, editor.2006.

4. Stunkard, A.J, Messick, S. The three-factor eating questionnaire to measure dietary restraint, disinhibition and hunger. J Psychosom Res 1985;29(1);71-83.